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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,372	03/12/2004	Jeffrey S. Mumm	15060-58	7301

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EXAMINER

BERTOGLIO, VALARIE E

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 12/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/799,372

Applicant(s)

MUMM ET AL.

Examiner

Valarie Bertoglio

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1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-30 is/are pending in the application.
- 4a) Of the above claim(s) 13-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>09-29-2006</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's reply dated 10/02/2006 has been received. Claims 1-12 have been cancelled. Claims 13-18 are withdrawn as being drawn to a non-elected invention. Claims 19-30 have been added. Claims 13-30 are pending and claims 19-30 are under consideration in the instant office action.

Specification

The previous objection to the disclosure is withdrawn in light of Applicant's amendment to the specification.

The disclosure is objected to because of the following informalities: The sentence at line 3 of paragraph [000257] appears to be incomplete. It is interpreted to read "Both plasmids are digested with AflII and AgeI".

Appropriate correction is required.

Claim Objections

The objection to claims 2-12 is withdrawn in light of Applicant's cancellation of the claims.

Claims 30 in their first and second occurrence are objected to because of the following informalities: Two claims are numbered as claim 30. This appears to be a typographical error. The first occurrence of claim 30 is presumed to be claim 29, because there is no claim numbered 29, and the second occurrence of the claim numbering 30 is presumed to be correct. Thus, the second claim numbered 30, which is written to depend from claim 30, is presumed to depend from the preceding claim which should be numbered 29 and is interpreted to depend from the first listed claim 30. Appropriate correction is required.

Claim Rejections - 35 USC § 112-1st paragraph

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The previous rejection of claims 1-9,11 and 12 under 35 U.S.C. 112, first paragraph, as lacking enablement for the full breadth of the claims is withdrawn in light of Applicant's arguments. In light of Applicant's support of a number of mammalian and frog promoters supporting tissue specific expression in fish, it would not require undue experimentation to determine non-fish promoters that express the transgenes in a manner sufficient to fulfill the uses of the instant invention. The invention requires low levels of expression to ablate a cell and fails to require any specific resulting phenotype that would not be enabled. While it is maintained that the art holds that use of non-fish promoters in transgenic fish is highly unpredictable, the nature of the instant invention allows for this unpredictability as one of skill in the art could routinely screen various promoters that provide sufficient expression to carry out the instant invention.

Written Description

Claim 25 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new grounds of rejection.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116).

Claim 25 lacks written description because in the instant case regulatory DNA sequences that drive specific expression to skeletal, cardiac, bone or cartilage cells of a medaka or zebrafish

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encompassed by the claims is not described. Applicant is claiming a cell wherein the critical element of the invention is a promoter driving gene expression to skeletal, cardiac, bone or cartilage cells. The specification describes a number of tissue-specific regulatory sequences but fails to describe that encompassed by claim 25. The specification and the art at the time of filing fails to describe what DNA molecules fall into this genus and it was unknown as of Applicants' effective filing date any DNA sequences that would have the property of driving gene expression to skeletal, cardiac, bone or cartilage cells in fish. Thus claimed embodiments of transgenic fish having cell specific expression in skeletal, cardiac, bone or cartilage cells is not described. The claimed invention as a whole is not adequately described if the claims require essential or critical elements that are not adequately described in the specification and that is not conventional in the art as of applicants effective filing date. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641,1646 (1998).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. § 112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 112-2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The previous rejection of claims 4-11 under 35 USC 112, 2nd paragraph is withdrawn in light of Applicant's cancellation of the claims.

Claims 19-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 19 is unclear as written for a number of reasons. First, the claim states that the transgene comprises an ablation-promoting moiety, which would indicate that the DNA is ablation promoting. However, the specification indicates that the transgene encodes an ablation-promoting moiety. The claim is interpreted as though the latter is the case. The final phrase of the sentence “the reproducible expression pattern is at least one of a spatial and temporal pattern” is also unclear as to what is intended. The phrase encompasses any expression whatsoever because any pattern even lack of expression, is a pattern.

An example of claim language that would obviate this rejection and would be more precise, includes “A transgenic zebrafish or medaka comprising a transgene encoding an ablation-promoting moiety operably linked to a regulatory sequence, wherein the ablation promoting moiety includes at least one component of a pro-drug conversion system, and wherein the transgene is expressed in a reproducible spatial and temporal pattern in the fish.” This claim language is not intended to recite allowable subject matter but to guide Applicant in overcoming the above issues of clarity while removing some awkward phraseology. Claims 20-26 depend from claim 19.

Claim 27 is unclear as written for a number of reasons. First, the claim states that the transgene comprises an ablation-promoting moiety, which would indicate that the DNA is ablation-promoting. However, the specification indicates that the transgene encodes an ablation-promoting moiety. The claim is interpreted as though the latter is the case. The final phrase of the sentence “wherein the transgene is expressed by the endogenous regulatory DNA sequence” also renders the claim unclear because cis-acting DNA regulatory sequences do not “express” a transgene. Rather, they guide, or drive, expression of a coding sequence. More clear language would include “Wherein expression of the transgene is regulated by...” Applicant is also referred to the preceding paragraph for suggested grammatical changes for this claim. Claims 28 depends from claim 27.

Claim 29 (originally claim 30 in its first occurrence) is unclear as written because the claim states that the transgene comprises an ablation-promoting moiety, which would indicate that the DNA is

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ablation-promoting. However, the specification indicates that the transgene encodes an ablation-promoting moiety. The claim is interpreted as though the latter is the case. Claim 30 in its second occurrence depends from this claim.

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Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Valarie Bertoglio
Examiner
Art Unit 1632